PATIENT ASSISTANCE PROGRAM
DATA SHARING AGREEMENT

USER GUIDE

Version Effective Date:
December 4, 2006

INTRODUCTION

This Patient Assistance Program (PAP) Data Sharing Agreement (DSA) **USER GUIDE** provides information and instructions PAPs will find useful as they implement and then manage the PAP information sharing process with CMS. In particular, a PAP DSA and the information in this User Guide will allow users to coordinate Medicare Part D drug benefits with CMS within the requirements of the Medicare Modernization Act (MMA).

PERIODICALLY, THE INFORMATION PROVIDED IN THIS USER GUIDE WILL CHANGE. As current requirements are refined and new processes developed, PAP partners will be provided with new and up-to-date sections of this Guide. These updated versions should replace any older versions of the Guide that you might have. Please contact the CMS should you have any questions regarding this User Guide.

If would like more general information about the current PAP process, please E-mail john.albert@cms.hhs.gov or william.decker@cms.hhs.gov . Remember to provide us with the E-mail address, phone number and other contact information for individuals you would like to have included in the reply.

SECTION A: COMPLETING AND SIGNING A PAP DSA

To make the PAP DSA relationship operational, the potential PAP DSA partner and CMS have to sign and exchange completed copies of the PAP DSA. Note that the Patient Assistance Program (PAP) Attestation to be used by Programs for Medicare Part D Enrollees Operating Outside the Part D Benefit must be signed and returned to CMS before the PAP DSA will be available for execution. (For information about the PAP Attestation process go to xxx.) These are the instructions for completing a PAP DSA for signature.

1. In the first paragraph of the PAP DSA, insert all of your specific identifying information where indicated. The latest date that both the partner and CMS complete the signature process will be entered here, and will be the "Effective Date." If you wish, the date you enter may be prospective or retroactive. For example, some PAP DSA partners may prefer to enter the first day of the month in which they expect the PAP DSA to be

signed. But bear in mind that if you enter a prospective date, CMS cannot begin full implementation of the PAP DSA until we reach it.

2. Enter the date that is requested on Page 3 of the PAP DSA, in Section C, 1. This is the starting date for PAP enrollment information that is entered in Field 7 on the first regular production Initial Input File you provide to CMS.

3. On Page 7, in Section I, enter the partner's Administrative and Technical contact information.

4. Page 8, Section J: Upon receipt of a PAP DSA signed by the partner, CMS will provide the required Technical contact information. This does not need to be completed to execute the Agreement.

5. In the footer starting on Page 1, and throughout the rest of the document, insert the partner's business name.

6. In the footer of the Implementation Questionnaire, insert the partner's business name.

The PAP DSA signature package consists of two documents: The PAP DSA itself, and the PAP DSA Implementation Questionnaire. The PAP DSA partner will return two signed copies of the PAP DSA and one completed copy of the Implementation Questionnaire to CMS. One copy of the PAP DSA will be signed by CMS and returned to the partner. If it wishes, the partner can ask that CMS sign the PAP DSA first. CMS will then provide two signed copies of the PAP DSA to the partner, and the partner will sign one copy and return it to CMS. But in either case CMS will not consider the PAP DSA to be in force until the partner has also provided CMS with a completed copy of the Implementation Questionnaire.

To avoid unnecessary processing delays, we strongly recommend that you use an overnight delivery service and send your PAP Data Sharing Agreement (s) and Implementation Questionnaire to:

John Albert
Centers for Medicare and Medicaid Services
OFM/FSG
Div. of Medicare Secondary Payer Policy and Operations
Mail Stop: C3-14-16
7500 Security Boulevard
Baltimore, Maryland 21244-1850

SECTION B: THE PAP DATA FILES

Standard Reporting Information

Standard Data Files: The data exchanged through the PAP process is arranged in two different file formats (also referred to as record layouts). A PAP partner electronically transmits a data file to CMS' *Coordination of Benefits Contractor*, referred to throughout this document as *the COBC*. The COBC processes the data in this *input file*, and at a prescribed time electronically transmits a *response file* to the partner. The *input file* is the method through which the PAP data sharing partner will submit its covered PAP enrollee population. In return, the COBC will send back a response file to the partner which will contain Medicare Part D enrollment information for all PAP enrollees who also have Part D.

Current versions of the Standard Data Files immediately follow. Once again we remind you that periodically the information provided here will change.

I. The Input and Response File Data Layouts

A. *The PAP Input Fi*le: This is the dataset transmitted from a PAP partner to the COBC on a monthly basis. It is used to report information regarding PAP enrollees – individuals who are eligible for and enrolled in a PAP and receive pharmaceutical coverage through such a plan. Full file replacement is the method used to update eligibility files. Each month's transmitted file will fully replace the previous month's file. The business rules for use of the PAP Input File immediately follow the data file layout itself.

PAP Input File Layout – Attachment A. 249 bytes

A – Patient Assistance Program Input File Layout – 249 bytes					
Field	**Name**	**Size**	**Displacement**	**Data Type**	**Description**
1.	SSN	9	1-9	Numeric	Social Security Number – Required Populate with spaces if unavailable.
2.	HICN	12	10-21	Alpha-Numeric	Medicare Health Insurance Claim Number Required if SSN not provided. Populate with spaces if unavailable.
3.	Surname	6	22-27	Text	Surname of Covered Individual - Required
4.	First Initial	1	28-28	Text	First Initial of Covered Individual - Required
5.	DOB	8	29-36	Date	Date of Birth of Covered Individual - Required CCYYMMDD
6.	Sex Code	1	37-37	Numeric	Sex of Covered Individual - Required 0: Unknown 1: Male 2: Female

A – Patient Assistance Program Input File Layout – 249 bytes					
Field	**Name**	**Size**	**Displacement**	**Data Type**	**Description**
7.	Effective Date	8	38-45	Date	Effective Date of PAP Coverage - Required CCYYMMDD
8.	Termination Date*	8	46-53	Date	Termination Date of PAP Coverage - Required CCYYMMDD *Use all zeros if open-ended
9.	N-Plan ID	10	54-63	Filler	**Future use**; for National Health Plan Identifier. Fill with spaces only
10.	Rx ID/Policy Number	20	64-83	Text	Covered Individual Pharmacy Benefit ID. Fill with spaces only.
11.	Rx Group	15	84-98	Text	Pharmacy Benefit Group Number. Fill with spaces only.
12.	Part D PCN	10	99-108	Text	Part D specific Pharmacy Benefit Processor Control Number. Fill with spaces only.
13.	Part D RxBIN	6	109-114	Text	Part D specific Pharmacy Benefit International Identification Number. Fill with spaces only.
14.	Toll-Free Number	18	115-132	Text plus "(" and ")"	Pharmacy Benefit Toll-Free Number. Fill with spaces only.
15.	Document Control Number	15	133-147	Text	Document Control Number Assigned by PAP- Required
16.	Coverage Type	1	148-148	Alpha-Numeric	Coverage Type Indicator - Required U: Network (electronic, point-of-sale benefit) V: Non-Network (other type of benefit)
17.	Insurance Type	1	149-149	Alpha-Numeric	Insurance Type - Required N: Non-qualified State Program O: Other P: PAP R: Charity S: ADAP
18.	Filler	100	150-249	Alpha-Numeric	Unused Field. Fill with spaces only
HEADER RECORD – All fields required					
1.	Header Indicator	2	1-2	Alpha-Numeric	Will be: 'H0'
2.	PAP-ID	5	3-7	Alpha-Numeric	PAP Identifier; starts with SA.

A – Patient Assistance Program Input File Layout – 249 bytes					
Field	**Name**	**Size**	**Displacement**	**Data Type**	**Description**
3.	Contractor Number	5	8-12	Alpha-Numeric	Will be: 'S0000'
4.	File Date	8	13-20	Date	CCYYMMDD
5.	Filler	229	21-249	Alpha-Numeric	Unused Field Fill with Spaces.
TRAILER RECORD – All fields required					
1.	Trailer Indicator	2	1-2	Alpha-Numeric	Will be: 'T0'
2.	PAP-ID	5	3-7	Alpha-Numeric	PAP Identifier; starts with SA.
3.	Contractor Number	5	8-12	Alpha-Numeric	Will be: 'S0000'
4.	File Date	8	13-20	Date	CCYYMMDD
5.	Record Count	9	21-29	Numeric	Number of records on file
6.	Filler	220	30-249	Alpha-Numeric	Unused Field Fill with Spaces.

B. *The PAP Response File*: This is the data set transmitted from the COBC to the PAP partner after the information supplied in the partner's PAP Input File has been processed by the COBC. It consists of the same data elements in the Input File, with corrections applied by the COBC, indicated by disposition and edit codes which let you know what we did with the record. The response file will also contain new information for the partner regarding the submitted PAP enrollees, including Medicare enrollment information if a match was found.

PAP Response File Layout – Attachment B. 417 bytes

B – Patient Assistance Program Response File Layout – 417 bytes					
Field	**Name**	**Size**	**Displacement**	**Data Type**	**Description**
1.	SSN	9	1-9	Alpha-Numeric	Social Security Number
2.	HICN	12	10-21	Alpha-Numeric	Medicare Health Insurance Claim Number
3.	Surname	6	22-27	Alpha-Numeric	Surname of Covered Individual
4.	First Initial	1	28-28	Alpha-Numeric	First Initial of Covered Individual

B – Patient Assistance Program Response File Layout – 417 bytes					
Field	**Name**	**Size**	**Displacement**	**Data Type**	**Description**
5.	DOB	8	29-36	Alpha-Numeric	Date of Birth of Covered Individual CCYYMMDD
6.	Sex Code	1	37-37	Alpha-Numeric	Sex of Covered Individual 0: Unknown 1: Male 2: Female
7.	Effective Date	8	38-45	Alpha-Numeric	Effective Date of PAP Coverage CCYYMMDD
8.	Termination Date*	8	46-53	Alpha-Numeric	Termination Date of PAP Coverage; CCYYMMDD *Use all zeros if open-ended
9.	N-Plan ID	10	54-63	Alpha-Numeric	**Future use**; for National Health Plan Identifier
10.	Rx ID	20	64-83	Alpha-Numeric	Covered Individual Pharmacy Benefit ID
11.	Rx Group	15	84-98	Alpha-Numeric	Pharmacy Benefit Group Number
12.	Part D PCN	10	99-108	Alpha-Numeric	Part D specific Pharmacy Benefit Processor Control Number
13.	Part D RxBIN	6	109-114	Alpha-Numeric	Part D specific Pharmacy Benefit International Identification Number
14.	Toll-Free Number	18	115-132	Alpha-Numeric	Pharmacy Benefit Toll-Free Number
15.	Original Document Control Number	15	133-147	Alpha-Numeric	Document Control Number Assigned by PAP
16.	COBC Document Control Number	15	148-162	Alpha-Numeric	Document Control Number Assigned by COBC
17.	Coverage Type	1	163-163	Alpha-Numeric`	Coverage Type Indicator U: Network (Electronic, Point-of-Sale Benefit) V: Non-Network (Other type of Benefit)
18.	Insurance Type	1	164-164	Alpha-Numeric	N: Non-qualified State Program O: Other P: PAP R: Charity S: ADAP
19.	Current Disposition Code	2	165-166	Alpha-Numeric	Rx Result from BENEMSTR/ MBD (Action taken by COBC).

B – Patient Assistance Program Response File Layout – 417 bytes					
Field	**Name**	**Size**	**Displacement**	**Data Type**	**Description**
20.	Current Disposition Date	8	167-174	Alpha-Numeric	Date of Rx Result from BENEMSTR/MBD (CCYYMMDD)
21.	Edit Code 1	4	175-178	Alpha-Numeric	Error Code
22.	Edit Code 2	4	179-182	Alpha-Numeric	Error Code
23.	Edit Code 3	4	183-186	Alpha-Numeric	Error Code
24.	Edit Code 4	4	187-190	Alpha-Numeric	Error Code
25.	Part D Eligibility Start Date	8	191-198	Alpha-Numeric	Earliest Date that Beneficiary is eligible to enroll in Part D – Refer to Field 46 for Part D Plan Enrollment Date CCYYMMDD
26.	Part D Eligibility Stop Date	8	199-206	Alpha-Numeric	Date Beneficiary is no longer eligible to receive Part D Benefits – Refer to Field 47 for Part D Plan Termination Date CCYYMMDD
27.	Medicare Beneficiary Date of Death	8	207-214	Alpha-Numeric	Medicare Beneficiary Date of Death CCYYMMDD
28.	Filler	8	215-222	Alpha-Numeric	Unused Field
29.	Filler	8	223-230	Alpha-Numeric	Unused Field
30.	Filler	3	231-233	Alpha-Numeric	Unused Field
31.	Filler	8	234-241	Alpha-Numeric	Unused Field
32.	Filler	1	242-242	Alpha-Numeric	Unused Field
33.	Filler	1	243-243	Alpha-Numeric	Unused Field
34.	Filler	1	244-244	Alpha-Numeric	Unused Field
35.	Filler	1	245-245	Alpha-Numeric	Unused Field
36.	Filler	1	246-246	Alpha-Numeric	Unused Field

B – Patient Assistance Program Response File Layout – 417 bytes					
Field	**Name**	**Size**	**Displacement**	**Data Type**	**Description**
37.	Filler	1	247-247	Alpha-Numeric	Unused Field
38.	Filler	1	248-248	Alpha-Numeric	Unused Field
39.	Filler	1	249-249	Alpha-Numeric	Unused Field
40.	Filler	1	250-250	Alpha-Numeric	Unused Field
41.	Filler	1	251-251	Alpha-Numeric	Unused Field
42.	Filler	2	252-253	Alpha-Numeric	Unused Field
43.	Filler	9	254-262	Alpha-Numeric	Unused Field
44.	Filler	8	263-270	Alpha-Numeric	Unused Field
45.	Current Medicare Part D Plan Contractor Number	5	271-275	Alpha-Numeric	Contractor Number of the Current Part D Plan in which the Beneficiary is Enrolled
46.	Current Part D Plan Enrollment Date	8	276-283	Alpha-Numeric	Effective Date of Coverage Provided by Current Medicare Part D Plan CCYYMMDD
47.	Current Part D Plan Termination Date	8	284-291	Alpha-Numeric	Termination Date of Coverage Provided by Current Medicare Part D Plan CCYYMMDD
48.	Filler	8	292-299	Alpha-Numeric	Unused Field
49.	Filler	8	300-307	Alpha-Numeric	Unused Field
50.	Filler	2	308-309	Alpha-Numeric	Unused Field
51.	Filler	2	310-311	Alpha-Numeric	Unused Field.
52.	PBP	3	312-314	Alpha-Numeric	Part D Plan Benefit Package (PBP)
53.	Filler	3	315-317	Alpha-Numeric	Unused Field
54.	Filler	1	318	Alpha-Numeric	Unused Field

B – Patient Assistance Program Response File Layout – 417 bytes					
Field	**Name**	**Size**	**Displacement**	**Data Type**	**Description**
55.	Filler	99	319-417	Alpha-Numeric	Unused Field.
HEADER RECORD					
1.	Header Indicator	2	1-2	Alpha-Numeric	Should be: 'H0'
2.	PAP-ID	5	3-7	Alpha-Numeric	PAP Identifier
3.	Contractor Number	5	8-12	Alpha-Numeric	Should be: 'S0000'
4.	File Date	8	13-20	Alpha-Numeric	CCYYMMDD
5.	Filler	397	21-417	Alpha-Numeric	Unused Field
TRAILER RECORD					
1.	Trailer Indicator	2	1-2	Alpha-Numeric	Should be: 'T0'
2.	PAP ID	5	3-7	Alpha-Numeric	PAP Identifier
3.	Contractor Number	5	8-12	Alpha-Numeric	Should be: 'S0000'
4.	File Date	8	13-20	Alpha-Numeric	CCYYMMDD
5.	Record Count	9	21-29	Alpha-Numeric	Number of records on file
6.	Filler	388	30-417	Alpha-Numeric	Unused Field

Data Type Key

Conventions for Describing Data Values. The table below describes the data types used by the COBC for its external interfaces (inbound and outbound). The Formatting Standards used with each data type correspond to the requirements of the interface layout.

This key is provided to augment the rules prescribing the formatting of data values that are provided within the PAP Data Exchange Layouts.

Data Type Key		
Data Type / Field	**Formatting Standard**	**Examples**
Numeric	• Zero through 9 (0 → 9) • Padded with leading zeroes • Populate empty fields with spaces	• Numeric (5): "12345" • Numeric (5): "00045" • Numeric (5): " "
Alpha	• A through Z • Left justified • Non-populated bytes padded with spaces	• Alpha (12): "TEST EXAMPLE" • Alpha (12): "EXAMPLE "
Alpha-Numeric	• A through Z (all alpha) + 0 through 9 (all numeric) • Left justified • Non-populated bytes padded with spaces	• Alphanum (8): "AB55823D" • Alphanum (8): "MM236 "
Text	• Left justified • Non-populated bytes padded with spaces • A through Z (all alpha) + 0 through 9 (all numeric) + special characters: • Comma (,) • Ampersand (&) • Space ( ) • Dash (-) • Period (.) • Single quote (') • Colon (:) • Semicolon (;) • Number (#) • Forward slash (/) • At sign (@)	• Text (8): "AB55823D" • Text (8): "XX299Y " • Text (18): "ADDRESS@DOMAIN.COM" • Text (12): " 800-555-1234" • Text (12): "#34 "
Date	• Format is field specific • Fill with all zeroes if empty (no spaces are permitted)	CCYYMMDD (e.g. "19991022") Open ended date: "00000000"
Filler	• Populate with spaces	
Internal Use	• Populate with spaces	
Above standards should be used unless otherwise noted in layouts		

II. The PAP Data Management Process

The information following describes the data review processes used by the Coordination of Benefits Contractor (COBC). The "System" is the COBC data processing system.

PAP Processing Requirements

The System shall be able to receive an external file from a PAP via a dedicated T-1 line (through AGNS), or via Secure File Transfer Protocol (SFTP) or HTTPS.

1. The System shall be able to confirm the external PAP file format.

2. The System shall check enrollee records that are received on the PAP file for the mandatory fields.

3. The System shall match enrollee records that are received on the PAP file to the Benefits Master Table.

4. The System shall be able to provide information pertaining to all prescription drug coverage information for Part D beneficiaries as stored on the Medicare Beneficiary Part D database, the MBD.

5. The System shall be able to create and transmit a file for processing by the MBD containing PAP enrollees with their specific Part D plan information.

6. The system shall be able to update the MBD table with information received on the PAP records.

7. The System shall be able to create and transmit a return file to the PAP containing response records. A response record is only generated when an add, update, or delete transaction is detected. The PAP partner will not receive response records for input records that produced no changes to existing data. The System shall be able to process a full-file replacement of the PAP records on a monthly basis.

Description

The purpose of this Patient Assistance Program process is to coordinate prescription drug benefits between Medicare Part D plans and PAPs as specifically required by the Medicare Modernization Act of 2003.

In order to coordinate benefit information, data must be collected from each PAP on each of its enrollees. Submission file formats have been created for PAP partners to deliver the pertinent information. This information from a PAP will be transmitted to the COBC where it will be edit-checked, and matched against Medicare data in various eligibility databases. Once a match is found, the COBC will be able to combine the beneficiary's PAP information with their personal Medicare Part D information to create a complete record of the beneficiaries' PAP and Medicare drug benefits.

The combined drug benefits information will be loaded into the Medicare Beneficiary Database (MBD). Data from the MBD will be transmitted to the Part D plans. An additional file format will be created to return to the PAP. It will contain one status response record for each record initially submitted by the PAP to the COBC. The response record will indicate if the PAP enrollee is a Part D beneficiary; whether or not the COBC applied the record to the MBD; if the record was not applied to the MBD, why not (e.g., the record contained errors or the record did not provide enough information about the enrollee); what Part D plan the beneficiary is in enrolled in; and other selected Part D enrollment information.

Disposition Codes

Listed below are the disposition codes that the COBC may provide in a Response File received by a PAP Partner. Disposition codes provide information about the general status of the data included in a Partner's Input Files.

DISPOSITION CODES	DESCRIPTION
01	Record **accepted** by CMS Systems, as an "Add" or a "Change" record.
SP	Transaction edit; record returned with at least one edit. Specific SP and RX edits are described below.
50	Record still being processed by CMS. Internal CMS use only*; no Partner action is required.*
51	Beneficiary is not on file with CMS. Record will not be recycled. Beneficiary most likely not entitled to Medicare. *Partner should reexamine Medicare beneficiary status based on information in its own files.*

Error Codes (SP and RX Edits)

The COBC will perform edit checks on the PAP Input File and will generate the following transaction error codes, as necessary. The COBC will supply the edit check results to the PAP. The PAP will be expected to correct any errors or update any missing information on its enrollees, and re-transmit the revised data on the following month's Input File submission. The SP errors that apply to PAP records are as follows:

Error Code	Description
SP 12	Invalid HIC Number or SSN. Field must contain alpha or numeric characters. Field cannot be blank or contain spaces.
SP 13	Invalid Beneficiary Surname. Field must contain alpha characters. Field cannot be blank, contain spaces or numeric characters.
SP 14	Invalid Beneficiary First Name Initial. Field must contain alpha characters. Field cannot be blank, contain spaces, numeric characters or punctuation marks.
SP 15	Invalid Beneficiary Date of Birth. Field must contain numeric characters. Field cannot be blank, contain spaces or alpha characters. Day of the month must be correct. For example, if month = 02 and date = 30, the record will reject.

Error Code	Description
SP 16	Invalid Beneficiary Sex Code. Field must contain numeric characters. Field cannot be blank, contain spaces or alpha characters. Acceptable numeric characters include the following: 1 = Male 2 = Female
SP 18	Invalid Document Control Number. Field cannot be blank. The PAP must assign each record a unique DC number in the event questions concerning a particular record arise and need to be addressed.
SP 24	Invalid Coverage Type. Field must contain alpha characters. Field cannot be blank or contain numeric characters. Valid values are: U: Network V: Non-network
SP 31	Invalid PAP Coverage Effective Date. Field must contain numeric characters. Field cannot be blank, contain spaces, alpha characters or all zeros. Number of days must correspond with the particular month. CCYYMMDD
SP 32*	Invalid PAP Coverage Termination Date. Field must contain numeric characters. Date must correspond with the particular month. Cannot be earlier than the PAP effective date. CCYYMMDD. *If there is no termination date (coverage is still active), must use zeros (not spaces) in this field.
SP 62	Incoming termination date is less than effective date.

Additionally, COBC will provide RX specific errors. NOTE: These are standard error, edit and disposition codes used by the COBC for processing drug records. However, most of these codes will not applicable to the PAP data sharing process.

Error Code	Description
RX 01	Missing RX ID
RX 02	Missing RX BIN
RX 03	Missing RX Group Number
RX 04	Missing Group Policy Number
RX 05	Missing Individual Policy Number
RX 07	Missing Part D Effective date

PAP Data Processing

1. Each month the PAP submits to the COBC an electronic input file of all its enrollees, via an existing T-1 line or over the Internet using Secure FTP or HTTPS.

2. The COBC edits the input file for consistency, and attempts to match the PAP enrollees with Medicare Part D enrollment.

3. Where the COBC determines that an enrollee on the PAP file is a Medicare Part D beneficiary, the COBC updates that record to the CMS Medicare Beneficiary Database (MBD). The MBD will send daily updates of all prescription drug coverage of Part D beneficiaries to the Part D plan that the beneficiary is enrolled in.

4. The COBC then submits a response file to the PAP via the same method the input file was submitted, i.e., via a T1 line or the Internet. This file contains a response record for each input record the PAP submitted. The response record shows if the PAP enrollee is a Part D beneficiary; if the COB contractor applied the record to the MBD; if the record was not applied to the MBD, and why (e.g., the record contained errors or the record did not provide enough information about the enrollee), in which Part D plan the beneficiary is enrolled, and other Part D enrollment information.

5. The PAP then examines the response file to determine whether: The records were applied to CMS systems; the COBC was not able to match the PAP enrollee in the CMS systems; or the records were not applied because of errors. The PAP must correct any defective records so that when they are included in future input files they can be applied to the MBD. Errors have to be corrected because the MBD must have accurate, up-to-date PAP coverage information.

6. The PAP updates its internal records regarding the Part D enrollment of its beneficiaries.

7. When the PAP submits its next monthly full input file, it includes corrections of all the errors found in its previous submission.

Business Rules for PAP Processing

1. The monthly Input File submitted by the PAP is a full-file-replacement file. The PAP's entire base of enrollees must be submitted each month on this file, and it must include any corrections to errors found in the previous month’s file. Each month’s input file will fully replace the previous month’s input file.

2. One Response File will be returned to each PAP, containing a response record for each input record received, unless the input record is unchanged. The disposition of the input record will be provided on its corresponding response record, including whether the record was accepted.

3. The COBC will attempt to create one record for each PAP enrollee record received.

4. The COBC will not send incomplete records to the MBD.

5. On all PAP Input Files the fields *required* are SSN or HICN, Surname, First Initial, Date of Birth, Sex Code, Network Indicator, PAP Effective Date, PAP Termination Date, Coverage Type Indicator, Insurance Type Indicator, and PAP – ID (in the header and trailer).

III. PAP Implementation Questionnaire – Attachment C

PAP Implementation Questionnaire – Attachment C. The Implementation Questionnaire asks a series of questions of the data sharing partner that helps the CMS and the partner set up the data sharing exchange process. These questions are intended to help you think through some of the issues which need to be addressed before you begin the data exchange and to assure that both the CMS and the PAP partner are in agreement as to the operational process involved. **PAP partners must fill out, sign and return a copy of the Questionnaire to the CMS with their signed PAP Data Sharing Agreement.** The Questionnaire is listed as Attachment C in the materials that accompany the Agreement sent to new PAP data sharing partners.

SECTION C: WORKING WITH THE DATA

I. Establishing Electronic Data Exchange

A number of methods of electronic data transmission are available when a partner is ready to exchange files with the Coordination of Benefits Contractor (COBC) in test or production modes. Following is an overview of the most common. The Partner's assigned Electronic Data Interchange Representative (EDI Rep) at the COBC will address a Partner's specific questions and concerns.

1. CMS' preferred method of electronic transmission is Connect:Direct (formerly known as Network Data Mover [NDM]) via the AT&T Global Network System (AGNS). Because AGNS is capable of transporting multiple protocol data streams to its members world wide, AGNS service removes the need to support a separate electronic link to each Partner. In addition, for encryption AGNS uses triple DES as its default.

Use of either SNA or TCP/IP is available to submitters connected to the AGNS network. FTP via TCP/IP on either a dial or dedicated basis via AGNS is also supported.

2. In addition, CMS has available two secure Internet transmission options, SFTP and HTTPS. We recommend either of these options for Partners that anticipate having a relatively low volume of data to transmit and that might find it is a burden to secure an AGNS connection. The PAP's assigned EDI Rep at the COBC can advise you on this option.

II. Testing the Data Exchange Process

Overview: Before transmitting its first "live" (full production) input file to the COBC, the partner and the COBC will thoroughly test the file transfer process. Prior to submitting its initial Input Files, the partner will submit a test initial Input File to the COBC. The COBC will return a test initial Response File. The COBC will correct errors identified in the partner's test files. Testing will be completed when the partner adds new enrollees in test update Input Files, the COBC clears these transmissions, and the partner and the COBC agree all testing has been satisfactorily completed.

Details: The partner and the COBC will begin testing as soon as possible, but no later than 180 days after the date the PAP DSA is in effect. The population size of a test file will not exceed 1000 records. All administrative and technical arrangements for sending and receiving test files will be made during the "Preparatory Period." See Section B in "Terms and Conditions" in the Patient Assistance Program Data Sharing Agreement.

Testing PAP Records: The test file record layouts used will be the regular PAP record layouts. Data provided in the test files will be kept in a test environment, and will not be used to update CMS databases. The PAP partner will produce and transmit a test "Add" Input File to the COBC. Upon completion of its review of the test file, the COBC will provide the partner with a response for every record found on it, usually within a week, but no longer than forty-five (45) days after receipt of the test file. After receiving the test Response File in return, the partner will take the steps necessary to correct the problems that were reported on it.

In order to test the process for creating an Update File, a test "Update" shall be prepared by the partner and include data regarding individuals identified in the test Add File. The partner shall submit the test Update data within ninety (90) days after receipt of its test Response File. The test Update File shall include any corrections made in the previous Test Response File sent to the partner by the COBC. With the full file replacement process used here, any corrections made to the file will fully replace what was previously submitted by the Partner. Upon completion of its review of the test Update File, the COBC shall provide the partner a Response for every record found on the Test Update File. The COBC will provide this Test Update Response File to the partner usually within a week, but no longer than forty-five (45) days after receipt of the partner's Test Update File.

After all file transmission testing has been completed to the satisfaction of both the PAP Data Sharing partner and CMS, the partner may begin submitting its regular production

files to the COBC, in accordance with the provisions of Sections V. C and V. D of the PAP Data Sharing Agreement.

III. PAP File Processing

On a monthly basis, PAPs will transmit full file submissions in the file format specified in the agreement. Full file processing requires the PAP to submit a complete file of enrollees every month. Each month's transmitted file will fully replace the previous month's file.

File and Record Level Editing

Upon the COBC's receipt of the PAP Input File, high-level file edits are performed to verify the format and validity of the Input File. High-level editing verifies Header and Trailer data and record counts. The size of the PAP Input File (the number of records contained in the file) is compared to the size of the previous monthly file submitted. The method for deleting enrollees in full file replacement processing is to not include enrollee files previously submitted. If the current file size is less then 70% of the previous month's file, the current Input File will be placed on hold and the PAP partner will be notified. The PAP partner will be asked to verify the high number of delete records in the current submission.

The Input File is then processed at the record level to determine if an incoming enrollee record is an add, update, delete, or if no action will be taken on it. The system initially attempts to convert an SSN to a HICN if a HICN is not submitted on the input file. (The HICN – Health Insurance Claim Number – is the Medicare ID Number.)

The COBC will only create a response record if a record has been added, or an existing record has been updated or deleted. An input record that has already been applied in a previous full file submission and is contained in the current submission unchanged (i.e., with no updates or errors) will not generate a response record. However, the COBC and CMS work to ensure that PAPs will receive updated Part D enrollment status in their monthly response files even if no other information about the affected beneficiary has changed.

Adds

Using the beneficiary's HICN, the incoming record is compared to the database to attempt to match on previously submitted records. The data elements comprising the set of initial matching criteria consist of the HICN, Effective Date, Insurance Type, and PAP ID. If a match of these fields cannot be made on the existing database, the incoming record is considered an "add."

Updates

If incoming field matches indicate a record is not an Add, additional fields are compared to determine if the incoming record should be considered an update. These fields include Toll-Free Number, Coverage Type, and Termination Date. If any of these fields have changed from the previous month's submission the record is considered an update. If the incoming record matches on these additional fields, no action is taken and the PAP does not receive a response for this record.

Deletes

Any records previously added, but not included in the PAP's current Input File submission, are processed as deleted records. Note that the delete process should only be used to remove a record that never should have been sent to CMS and added in the first place.

A beneficiary record that has been correctly added is required to be kept active for 27 months after benefit activity has ceased or been terminated. Consequently, Input Files should contain records of all beneficiaries whose PAP enrollment terminated up to twenty-seven (27) months prior to the first day of the month in which the new Input File is generated, or whose PAP enrollment terminated after December 31, 2005, whichever date is most recent. Failure to continue submitting these older valid records will cause them to be erroneously deleted from the CMS database.

Errors

Records containing errors are returned to the PAP with the appropriate error code on the response record linked to the erroneous input data. The PAP should identify and correct the error, and resubmit the record with the next month's regular Input File.

Notification to the Medicare Beneficiary Database (MBD)

When processing of incoming data is complete, a file is created and transmitted to MBD containing the adds, updates, and delete records generated by the COBC from the Input File submitted by the PAP. The MBD returns a file to the COBC containing Part D enrollment information.

Response Files

Within 15 days of the PAP Input File submission, the COBC generates and transmits a Response File to the PAP. This file contains responses for any records that were added, updated, or deleted. The file does not contain responses for records to which no change was made. The Response File also contains the Part D enrollment information received from the MBD.

IV. Distinction between Part D Eligibility and Enrollment

Some of our data sharing partners have expressed uncertainty regarding the difference between the Part D Eligibility Start and Stop Dates and Current Part D Plan Enrollment and Termination Dates they receive on their response files. While many use these terms interchangeably, these terms have distinct meanings for the Centers for Medicare & Medicaid Services' (CMS) data exchange process. To clarify:

Part D Eligibility Start Date (Field 25): Refers to the first date a beneficiary can enroll in a Part D Plan. It does not mean that the beneficiary actually has coverage, just that because of their current Part A or B coverage they can enroll in a Part D Plan.

Part D Eligibility Stop Date (Field 26): Refers to the date that the beneficiary is no longer eligible to enroll and receive coverage from any Part D Plan.

Current Part D Plan Enrollment Date (Field 46): Refers to a Medicare beneficiary that is eligible, has applied for and has coverage through a Part D Plan.

Current Part D Plan Termination Date (Field 47): Refers to the date that beneficiary is no longer receiving benefits under the Part D Plan.

In the response files the COBC sends you, the Current Part D Plan Enrollment Date provides the effective date of coverage for the Part D benefit by the specific Part D Plan listed as the Current Medicare Part D Plan Contractor Number (Field 45). The Current Part D Plan Termination Date is the date that beneficiary is no longer receiving benefits under that Part D Plan.

These dates are the most important for our data sharing partners because they let you know whether the beneficiary has actually elected coverage under Part D and the time period in which the Part D coverage became effective. In summary, a Medicare beneficiary can be eligible for Part D, but unless the beneficiary is enrolled in a Part D Plan, the beneficiary is not receiving Part D benefits.

V. Using Basis for Queries

When a partner has an immediate need to access Medicare eligibility and enrollment information, BASIS – the Beneficiary Automated Status and Inquiry System – permits a partner to make on-line queries to CMS to find out if it is possible that an individual is eligible for or enrolled in Medicare. Using a private, Web-based host, the PAP data sharing partner can use BASIS to access Medicare Part D enrollment data. Access to BASIS will be unlimited for our PAP partners until our unsolicited response enhancement becomes available in 2007. Once unsolicited responses are being generated, use of BASIS will be restricted to 200 queries per month.

Access to BASIS is contingent on the partner having submitted its Initial Input File and its most recent Update File during its latest monthly production cycle. Partners not submitting regularly scheduled Input Files will not have access to BASIS.

In overview, BASIS operates as follows:

1. The COBC assigns each partner its own PAP BASIS Personal Identification Number. The PAP BASIS ID is delivered to the designated PAP Contact Person within 30 days of submission of the partner's initial Input Files. At this time, the partner will also receive information concerning the designated telephone line to be used for the BASIS application.

2. CMS shall notify the partner when the BASIS program is operational and will provide detailed instructions on how to use the BASIS application.

3. The partner will dial a designated telephone line to access the BASIS application, using its assigned BASIS ID. For each PAP Enrollee for whom the partner is requesting Medicare enrollment information, the partner will enter the following data elements that identify the subject of the query:

    - Social Security Number
    - Last Name
    - First Initial
    - Date of Birth
    - Sex
    - HICN (optional)

4. CMS will post the results of inquiry(s) to BASIS within forty-eight (48) hours after the partner submits its inquiry(s) to the BASIS application.

VI. Obtaining a TrOOP Facilitation RxBIN or PCN – *If Necessary*

Most PAP partners **WILL NOT** need to obtain an RxBIN or PCN code number to enable coordination in support of the TrOOP process (which records Medicare beneficiaries' true out-of-pocket spending). This is because most PAPs will be providing assistance outside of the Medicare Part D benefit structure, and thus will not need to be concerned with Part D's TrOOP tracking requirements.

If your PAP believes it does, or should, operate within Medicare's Part D Program, you will need to function under the terms of a different data sharing agreement. Please contact either Mr. John Albert, John.Albert@cms.hhs.com , 410-786-7457; or Mr. William Decker, William.Decker@cms.hhs.gov , 410-786-0125; at CMS for more information.

SECTION D: QUESTIONS AND ANSWERS

PATIENT ASSISTANCE PROGRAM DATA SHARING AGREEMENT

FREQUENTLY ASKED QUESTIONS

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General Questions

Q1: What methods are available to me to use to communicate electronically with the Coordination of Benefits Contractor (COBC) in the data exchange process? Who is responsible for providing the necessary technology? Are there any alternatives?

A1: A PAP can use existing T-1 capability, or it can submit files over the Internet via secure File Transfer Protocol (SFTP) or HTTPS. CMS supports Sterling Commerce's Gentran Integration Suite 4.0 B2B for Multi-Enterprise Collaboration (GIS B2B Suite), via the internet or an existing T-1 line. For more information about Sterling products visit their website at www.sterlingcommerce.com/Products/AllProducts/Gentran/integrationsuite.html If you wish to establish a dedicated line you will need to contact one of our resellers to obtain a dedicated or dial-up access line to the managed AGNS VAN. Also, see Section C, I, on Page 15.

Files may also be transferred on CDs, although physical media is our last choice for effecting data exchanges. Such media is physically insecure, and it presents confidentiality and privacy risks that are avoided with electronic submissions over a T-1 line or via secure Internet connections. CMS will also soon be required to encrypt data exchanged on physical media. You may work on this issue with the EDI representative assigned to you once implementation begins, but be aware that the COBC is unlikely to continue to support use of physical media in the near future.

Q2: When will a PAP Partner Identification ID Code be assigned?

A2: The PAP ID will be assigned once the COBC has received a signed copy of the Data Sharing Agreement (DSA) from the PAP data sharing partner. This signature copy is sent to the COBC from CMS.

Q3: The COBC – PAP data exchange is a monthly process. What is the schedule for this process? Will the data exchange happen at the beginning, middle or end of month?

A3: Scheduling transmission of files depends upon when the agreement is signed. There is no requirement that each PAP have the same schedule. The COBC will work with each PAP partner during the Preparatory Period to set up a data production schedule.

Q4: Why is it necessary for the PAP to send records on beneficiaries for up to twenty-seven months after PAP eligibility or program participation has been terminated?

A4: The twenty-seven month submission requirement is necessary because that is the length of time Medicare claims can be active after a particular date of service. If a PAP participant record is sent one month, but not the next, the COBC will delete the record. If that happens, CMS loses the ability to link PAP and Medicare program service dates.

Q5: With regard to the Administrative and Technical contacts needed for the PAP - CMS data exchange, must either or both of these contacts be PAP staff or may they be contractor staff?

A5: The PAP can designate whomever it wishes as the administrative and technical contacts, including contractor staff, but only a duly authorized representative of the PAP can sign the actual PAP Data Sharing Agreement.

Q6: What are the requirements that must be met in order to successfully complete the PAP data sharing exchange testing process?

A6: CMS requires the PAP partner to be able to successfully (1) submit an initial and update test Input Files that can be processed to the satisfaction of the COBC, and; (2) receive and process a test Response File from the COBC. The COBC has been delegated the authority to determine whether or not the PAP partner has successfully completed the testing process to the satisfaction of CMS.

Data Elements

Q1: When the PAP submits a monthly full input file, it incorporates the corrections of all the errors from the previous submission. Are we sending the full file (all PAP eligible enrollees)?

A1: Yes, you send a full file.

Q2: Should we exclude previously matched records?

A2: No, you should include previously matched records.

Q3: Are "errors" just data discrepancies (e.g., a mismatched SSN)?

A3: Reports of errors can include data that is defective or that contains an invalid value, such as an alpha character in a field requiring a numeric date. The reported problem could also be due to a programming error. In any case, the error will be identified in the Response File using standard error codes.

Q4: Will we be receiving Medicare D enrollment information only, or will we be receiving information on all the other prescription coverage carried by the PAP client?

A4: We will provide only Medicare Part D enrollment information for your submitted PAP Program enrollees.

Q5: What field is identifying Medicare D enrollment?

A5: The Current Medicare Part D Plan Enrollment Date (Field 46 in the PAP Response File Layout) identifies enrollment in a Medicare Part D Plan.

Q6: What field identifies the Medicare Part D Plan?

A6: The Current Medicare Part D Plan Contractor Number (Field 45 in the PAP Response File Layout) identifies, by Contractor Number (not by name), the Part D Plan that the beneficiary is enrolled in.

Q7: If additional "other insurer" information is being sent, what field will identify the other insurer?

A7: You will only receive Medicare Part D enrollment information on the covered individuals that you submit and for whom the COBC finds a match. CMS does not provide you with other insurer information; we can only provide a PAP with Medicare Part D enrollment data.

Q8: We currently do not mandate collection of an SSN from the participant, although most of our participants have a SSN. In the cases where we do not have a SSN, do we send the information we have with the input file? If so, do we zero fill the information or leave it blank?

A8: The SSN or the HICN – the Health Insurance Claim Number (known more generally as the Medicare ID number) – is our primary identifier for matching to individuals that you submitted to determine their Medicare entitlement information. If you do not have either one of these numbers, you should not submit the subject record. We cannot perform our matching process without either the HICN or the SSN.

Q9: Is the Part D RxBIN and PCN the information that is identifying the Part D carrier or is it being used to identify other insurance as well?

A9: No, this information does not identify the Part D carrier (or any other insurer). The Current Part D Plan Contractor Number (Field 45 of the PAP Response File Layout for Part D) specifically identifies the particular Part D Plan that a beneficiary is enrolled in. The Part D PCN and Part D RxBIN are code numbers used to electronically route Part D network pharmacy benefit utilization information. Almost all PAPs are not involved in this "network pharmacy" process, so this information will not apply to PAPs.

Q10: What does the disposition code identify? Is this simply a "Yes or No" indication of coverage on the MBD?

A10: The Current Disposition Code (Field 19) lets you know what action the COBC has taken regarding the submitted record. For instance, if the record is not found, the COBC will provide the PAP data sharing partner with a disposition code that indicates that the record provided was not found. Additionally if a record is not applied due to errors, the disposition code provides you with this information.

Q12: What is the Plan Benefit Package code (Field 52) used for?

A12: PAPs should ignore this field. A Part D Plan may offer a variety of separately coded benefit packages, but since a PAP is not a Part D Plan there is no logic to this number for a PAP. (The PAP Response File layout was adapted from a layout used in another DSA program, and this field is an unavoidable remnant.)

Q13: Are PAP's eligible for the N-Plan ID?

A13: The N-Plan ID field is only a place-holder, for future use by insurers. PAPs can ignore this field.

Q14: Will you provide BASIS screen illustrations?

A14: BASIS implementation information is provided after the partner has signed the DSA and production data exchanges have begun. BASIS information will be provided by the COBC once production has started.

Q15: Are we to send all of our PAP enrollees in input files (including non-Medicare covered individuals), or only those who have told us that they have Medicare and may be in a Part D plan?

A15: We do not expect you to know of all your enrollees who are Part D beneficiaries. You can think of your first production Input File as a finder file. You send us all of your enrollees and we respond with a file indicating those we matched on and applied to our databases; matched on but didn't apply because of errors in the file; or did not match on and therefore are not beneficiaries.